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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,674	07/14/2006	Marcel Wijlaars	0470-060131	1707

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EXAMINER	
HELM, CARALYNNE E	
ART UNIT	PAPER NUMBER
1615	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,674	WIJLAARS ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Note to Applicant: References to paragraphs in non-patent literature refers to full paragraphs (e.g. 'page 1 column 1 paragraph 1' refers to the first full paragraph on page 1 in column 1 of the reference).

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 8, 2009 has been entered.

NEW REJECTIONS

Claim Objections

Claims 12 and 13 are objected to because of the following informalities: Claim 12 recites "swellable fibres comprise saturated in a liquid" which claim 13 recites "swellable fibres comprise fibres a polyurethane material". Neither of these recitations is completely coherent and appears to be missing words. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8-9 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malmonge et al. (previously cited) in view of Slivka et al. (Tissue Engineering 2001 7:767-780), Pissis et al. (previously cited) and Young et al. (previously cited).

Malmonge et al. teach a copolymer of 2-hydroxyethyl methacrylate (HEMA) and acrylic acid (AA) as artificial articular cartilage in a joint prosthesis (see page 175 column 1 paragraph 2-3; instant claims 8, 9, and 14). They go on to teach that the hydrogels made of this material have negative (ionized) groups fixed within the macromolecular network that are believed to participate in compressive strength of the material (see page 174 column 2 paragraph 1 line15-page 175 column 1 line 5 and page 175 column 1 paragraphs 2-3; instant claim 8). Ionized groups were therefore added to the hydrogel prior to polymerization and were present after polymerization (see page 176 column 1 paragraph 1; instant claim 8). Malmonge et al. also teach the ratio of HEMA to AA in the polymer to be 97.5 to 2.5 as well as 95 to 5 (see page 175 column 1 paragraph 4; instant claim 8). Malmonge et al. do not teach whether this ratio is based upon mass or moles. In the case where the ratio described the molar balance, the corresponding mass percentage of AA in the polymer would be 1.8% (mass percentage corresponding to 2.5 mol%) and 3.6% (mass percentage corresponding to 5 mol%), as calculated by the examiner. Further, Malmonge et al. also teach the hydrogel

being soaked (saturated) in a liquid solution (see figure 1 and caption; instant claim 12). Malmonge et al. do not teach the incorporation of fibers into the taught hydrogel.

Slivka et al. teach a fiber reinforced gel structure for articular cartilage repair. Other known repair materials are taught to frequently lack mechanical properties to ensure long term efficacy and could lead to inadequate support during healing (see page 767 paragraph 1). Specifically, Slivka et al. teach that a polymer solution is combined with polymer fibers sized at 2.5 mm in length such that a gel was formed (see page 770 paragraph 1). The fibers are taught to be present at 5%, 10%, 15%, and 20% (see figure 2). As the fiber loading increased, the compressive modulus and yield strength increased, indicating an improvement in mechanical properties due to the presence of these fibers (see figure 7). In addition, Slivka et al. point to the 10% fiber loading as particularly good for its slightly higher stiffness as compared to native tissue (see page 778 paragraph 1).

Pissis et al. teach the incorporation of Nylon particles (fibers), a swellable polyurethane, into a poly(hydroxylethyl acrylate) hydrogel (see page 561 paragraph 1; instant claims 8 and 13). Pissis et al. also teach that all polymer hydrogels would benefit from having their mechanical properties improved and that the inclusion of the Nylon serves this purpose (see page 561 paragraph 1; instant claims 8 and 13). Further Pissis et al. teach the inclusion of the Nylon particles at 10% (see page 561 paragraph 2 lines 17-18; instant claims 8 and 13).

Young et al. teach a fiber reinforced polyHEMA as a biomaterial (see abstract and page 1745 column 2 lines 6-13). Specifically Young et al. teach that due to the

capability of hydrogels to absorb large amounts of water, their polymer networks and mechanical strength can be compromised in the process (see page 1745 column1 lines 7). Young et al. go on to teach fiber reinforcement, the inclusion of fibrous material within the hydrogel, to improve the mechanical properties of these otherwise very versatile materials (see page 1745 column 1 line18-column 2 line 5). Further, Young et al. teach a nylon and elastic spandex fiber mesh as one utilized fiber reinforcement (see page 1746 column 1 lines 10-14 and figure 2). As demonstrated by the microscopic images provided, the fibers in this mesh were longer than one millimeter (see figure 2 panel c and panel d); instant claim 8)

Slivka et al. explicitly teach the inclusion of polymer fibers of at least one millimeter in length at 10% to 70% in a gel construct to improve its mechanical properties, which like Malmonge et al., is intended for articular cartilage repair. Therefore one of ordinary skill in the art would have been motivated to apply the same approach to improve the gel of Malmonge et al. since it also requires mechanical strength and integrity to function for its intended purpose as articular cartilage. Since both Pissis et al. and Young et al. teach fiber reinforcement in hydroxylated acrylate based hydrogel medical devices and Young et al. specifically teach their ability to mechanically reinforce such structures, it would have been obvious to one of ordinary skill in the art at the time of the invention to embed a fiber mesh, as taught by Young et al., in the HEMA—AA hydrogel prosthesis of Malmonge et al. Further, since both Slivka et al. and Pissis et al. provide a known proportion of gel to mesh in such devices and Young et al. provide known varieties and dimensions of mesh used to reinforce a

hydroges in biomaterials, one of ordinary skill would have also found it obvious to embed nylon/spandex fibers longer than one millimeter and composing approximately 10% of the hydrogel composite in the hydrogel composition of Malmonge et al. (applying a known technique to a known device ready for improvement to yield a predictable result/ use of known technique to improve similar devices in the same way). Consequently, the saturation of the Slivka et al., Pissis et al., and Young et al. modified gel of Malmonge et al. would also have the swellable nylon/spandex fibers saturated as well (see Malmonge et al. figure 1 and caption; instant claim 12). Therefore claims 8-9 and 12-14 are obvious over Malmonge et al. in view of Slivka et al., Pissis et al., and Young et al.

Claims 8 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malmonge et al. in view of Slivka et al., Pissis et al., and Young et al. as applied to claims 8-9 and 12-14 above, and further in view of Kou et al. (previously cited).

The teachings of Malmonge et al. in view of Slivka et al., Pissis et al. and Young et al. make obvious a HEMA-AA hydrogel with 10% Nylon/spandex fibers (dry weight), such that the AA content was from 1-5% (dry weight). However, this modified reference does not teach the use of methacrylic acid (MA) in the hydrogel.

Kou et al. teach a HEMA-MA hydrogel as being known in the art at the time of invention (see page 241 column 1 paragraph 1; instant claims 8 and 10). Further, the MA only differs from the AA in that it has an additional methyl group in the place of a hydrogen atom. Thus in a hydrogel, HEMA-MA would have negative groups fixed within

its macromolecular network like HEMA-AA. "Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH2- groups)are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977). See also In re May, 574 F.2d 1082, 197 USPQ 601(CCPA 1978) (stereoisomers prima facie obvious)." In addition, the MPEP cites Deuel, 51 F.3d at1558, 34 USPQ2d at 1214 and states that, "Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties." (see MPEP 2144.08). It would therefore be obvious to one of ordinary skill in the art at the time the invention was made to employ HEMA-MA in place of the HEMAA-AA taught by Malmonge et al. in view of Slivka et al., Pissis et al., and Young et al. It also would have been obvious for one of ordinary skill in the art to pursue known options within their technical grasp and use HEMA-MA instead of HEMA-AA in the Slivka et al., Pissis et al., and Young et al. modified hydrogel of Malmonge et al. Additionally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the monomer ratios taught by Malmonge et al. where MA replaces AA. Therefore claims 8 and 10 are obvious over Malmonge et al. in view of Slivka et al., Pissis et al., Young et al., and Kou et al.

Response to Arguments

Applicants' arguments and declaration, filed June 8, 2009, have been fully considered but they are not deemed to be persuasive.

Applicant provides arguments highlighting that each of the references cited do not individually teach each limitation of the instant claims. Such arguments are in no way persuasive. All the prior art rejections presented were based upon a combination of references specifically because the individual references did not teach all the claimed limitations by themselves.

Regarding rejection under 35 USC 1039a) over Malmonge et al. in view of Young et al. and Pissis et al.:

Applicant argues that the rejection did not provide evidence that a person of ordinary skill in the art would have combined the particular references cited. This is not an accurate characterization of the rejection since it explicitly stated the reasoning for applying the teachings of Pissis et al. and Young et al. in the invention of Malmonge et al. The rejection stated "[t]he hydrogel device taught by Malmonge et al. requires mechanical strength and integrity to function for its intended purpose as a joint prosthesis. Since both Pissis et al. and Young et al. teach fiber mesh reinforcement in hydrogel medical devices and Young et al. specifically teach their ability to mechanically reinforce such structures, it would have been obvious to one of ordinary skill in the art at

the time of the invention to embed a fiber mesh in the HEMA—AA hydrogel prosthesis of Malmonge et al." Both Pissis et al. and Young et al. explicitly teach the limitations of hydrogels due to their poor mechanical integrity particularly when swollen with water (see Young et al. page 1745 column 1 paragraph 1 and Pissis et al. page 561 paragraph 1). Since the intended use of the invention of Malmonge et al. is as an articular cartilage replacement it must have mechanical integrity in order to function and this would have been well known by one of ordinary skill in the art at the time of the invention (see Slivka et al.) Hydrogels alone were known not to maintain their mechanical integrity when swollen, as it would be in the physiological environment, thus it would have been obvious to one of ordinary skill to employ some means to ameliorate this limit. The teachings of Young et al. and Pissis et al. provide the same approach to this end, that being avenues of fiber reinforcement.

Both the arguments and declaration note that Malmonge et al. does not teach the presence of fibers in their gel. This was also noted in the rejection; however, it is not necessary for Malmonge et al. to explicitly teach the presence of fibers if the prior art and/or the knowledge of one of ordinary skill in the art provides motivation for their inclusion. While exhibit B demonstrates different mechanical properties in a un-reinforced gel as compared to a fiber reinforced gel it is not clear if the fiber reinforced gel was made in accordance with the invention or if the result is unexpected. Generally, it would be expected that the inclusion of fibers in a gel would give it better mechanical properties than an un-reinforced gel.

Applicant and the declaration argue that Pissis et al. teach away from the invention, citing elements that are not instantly claimed (e.g. uptake of monomer solution by fibers). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The declaration states that Pissis et al. teach away from including larger sized particles; however, this is not the case. The only limitation taught by Pissis et al. regarding the particulate reinforcing material is the proportion that can be included when used at the size they employed. Contrary to the assertion of the declaration, the interpretation of "nanoparticles" as "fibres" is not erroneous since no length dimension is inherent to the term "fibre". Instead, this interpretation is within the boundaries of a broad and reasonable interpretation of the claim language, as detailed in MPEP 2106 II B ("USPTO personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure."). Further, while Pissis et al. is concerned with ascertaining hydrogel properties beyond the scope of the invention, their general teachings are still relevant to the instant invention because they establish the need for fiber reinforcement in hydrogels and a general means by which to achieve it (e.g. incorporation of particulate material that can be included at 10%).

Applicant and the declaration again argue elements that are not claimed (e.g. compressive strength) in arguments against the relevance of Young et al. toward the instant invention. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988

F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Young et al. provides a motivation for including fiber reinforcement in hydrogels used in a biological context. The instant claims do not require a particular thickness for the claimed construct or architecture for the fibers, so the teachings of Young et al. that teach a woven set of fibers and a thin construct are still applicable to the instant invention.

Paragraph nine of the declaration states, "even if the skilled person would consider Pissis and/or Young, he would not arrive at the claimed invention. Instead, he would at most come up with a composite comprising very small amounts (<10 wt%, Pissis; <1.66 wt%, Young) of nanometer-sized particles (Pissis) or flat, ultrathin (<0.23 mm) woven or knitted nylon or spandex fibers (Young)…In this respect, any reasoning leading to other forms of fiber reinforcement, such as those with large (> 10 wt%) amounts of millimeter-sized fibers, would reflect impermissible hindsight bias." This compilation of the prior art is not quite accurate. Pissis et al. explicitly teaches and includes a 10% particle loading in their composition and Young et al. demonstrate that the length/width of the mesh fibers is at least 1 millimeter (note: figure 2c with its looped spandex fibers that in this state still span at least a millimeter – see scale bar -, in spite of the fact that the construct thickness/depth was only 0.24 millimeters). So the combination of references would actually teach a composite with 10% spandex fibers that are at least one millimeter in length, as instantly claimed (note instant claim 1 does not exclude the boundaries of the recited range of 10-70% m/m). Therefore impermissible hindsight is not necessary to achieve the invention for the prior art.

Regarding rejection under 35 USC 103(a) over Malmonge et al. in view of Young et al., Pissis et al., and Kou et al.:

Applicant and the declaration argue the combination of Malmonge et al. in view of Pissis et al. and Kou et al. reiterating previous arguments against Malmonge et al. and Pissis et al. and further argue that Kou et al. does not resolve their deficiencies and does not suggest the use of long fibers for applicant's intended purpose. Applicant does not include discussion of the fourth reference, Young et al., which was also included in the rejection. Therefore at the onset, these arguments are moot. Applicant goes on to argue elements that are not instantly claimed (e.g. durability of the hydrogel and improving toughness). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further it is not necessary that the prior art suggest the combination of components to achieve the same advantage or result recognized by applicant (see MPEP 2144 IV).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

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